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14. ABSTRACT

Following surgery or radiation of primary early-stage prostate cancer (PrCA), one in three patients will experience an elevation in serum prostate antigen (PSA) within 10 years. This rises to one in two at 15 years. After such evidence of recurrence, the most common treatment is androgen ablation. We hypothesize that the host-PrCA balance in asymptomatic men with biochemically recurrent PrCA, as reflected by the PSA rise, is favorably affected by an intensive, vegetable-based diet, plus physical activity and mindfulness-based stress reduction. This randomized trial will enroll 60 men with rising PSA levels along with a partner of their choice, half of whom will be randomized to the intervention and half to usual care. The intervention will continue for 3 months, followed by monthly booster sessions for 3 months. Data will be collected on main study outcomes, protocol compliance and adherence, and potential effect modifiers, mediators, and confounders of treatment effect.

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Introduction:

Prostate cancer (PrCA) is the most commonly occurring cancer, excluding skin cancer, in Western male populations (1). South Carolina, an area of high prostate cancer incidence, has the highest mortality rate of the disease in the world (2, 3). Generally, patients who present with prostate cancer are treated with either radical prostatectomy or radiation therapy. However, biochemically defined recurrence, marked by a rise in prostate-specific antigen (PSA), and the development of metastatic disease is common. No curative therapy exists for metastatic prostate cancer (4). Androgen ablation, the most commonly used management strategy, produces side effects whose severity has motivated a search for new strategies that could retard tumor progression and postpone the use of such therapy (5-7). Epidemiologic and laboratory studies suggest that environmental influences may be the most important modifiable PrCA-related risk factors. A more complete discussion of these issues can be found in the complete study protocol.

This randomized trial will evaluate the effects of such environmental influences on PSA rise, quality of life, and circadian organization. The focus will be on the effects of a vegetable-based diet, circadian-timed physical activity, and mindfulness stress reduction. Previous studies suggest these factors promote favorable outcomes in the host-prostate cancer balance. Asymptomatic men with rising PSA values following primary PrCA treatment along with a partner of choice are being recruited from the Palmetto Health system and the greater Columbia, SC area. Results from this study will add to our body of knowledge of the modifiable risk factors associated with the progression of prostate cancer.

Specific Aims:

Previous studies with both animal and human models suggest diet, physical activity, and stress reduction produce favorable results within the host-prostate cancer balance in asymptomatic men with rising concentrations of prostate-specific antigen (PSA) following primary PrCA treatment. This study will evaluate how the host-PrCA balance, as reflected by PSA rise, the span until symptom appearance, the robustness of circadian activity/sleep and melatonin patterns, and quality of life, is affected by an intervention consisting of:

- a whole-grain diet rich in soy products, other beans, and vegetables;
- a physical activity regimen aimed at increasing fitness and general well-being and establishing and maintaining the circadian coordination of the subject's sleep/activity cycle; and
- a mindfulness-based stress reduction aimed at increasing the coping resources of participants in dealing with difficult emotional reactions to a PrCA recurrence and related physical symptoms, and to increase compliance with other components of the intervention (i.e. to use meditation and other stress reduction techniques to increase self efficacy or the belief in the subject's own ability to change his other health-related behaviors for the better).

The purpose of this study was to test the effect on PSA levels of an intensive intervention combining diet, physical activity, and mindfulness-based stress reduction in prostatectomized (by either surgery or radiation or both) men after biochemical recurrence of prostate cancer. In order to assess the effect of the intervention on PSA rates of change and doubling times from the pre-recruitment period to the end of the intervention, subjects were be compared to age-matched controls randomized to usual care.

Body:

The approved Statement of Work categorized the work objectives for the project into 5 distinct tasks, each with indications for the months from the study timeline in which these tasks will be accomplished. Due to unforeseen delays in getting Human Subjects approval from the Institutional Review Boards of the three bodies governing this research (i.e., U.S. Army, University of South Carolina, and Palmetto Health), the original study timeline was revised. The original timeline started in May 2003 (month 1) and participant recruitment was scheduled to begin in August 2003 (month 5). Final approval from all three institutions was not obtained until late March 2004, with recruitment for the first wave of participants beginning immediately after.

With the start of recruitment, data became available on the number of men contacted, the number of responses received from contacts, the number of ineligibles and the number of eligibles. We had promising results in the beginning of recruitment with the referrals from urologists. We then had to explore other avenues in order to recruit participants. We focused our recruitment efforts on advertisements and health fairs, along with expanding our efforts to the surrounding Midlands areas. We also focused our efforts on recruitment of the African-American population through various publications widely read in that population.

In the following sections, each individual sub-task outlined in the Statement of Work is indicated in bold text and by an alphabetic indicator (e.g., a, b, c,…). Our work to accomplish these sub-tasks follows in bulleted form. Where applicable, problems encountered in completing tasks are described and how we overcame these barriers are outlined.

Task 1: Run-in Phase, Months 1-4:

a. Inventory and finalize all assessment instruments and data collection protocols.

- Accelerometers were purchased from MTI Actigraph. Analysis programs were provided by Dr. Chuck Matthews to analyze the Actigraph data for physical activity at baseline and six months. Instruction sheets for the proper use and return of the Actigraphs was prepared for participants. To ensure that we received the Actigraphs in a timely fashion, half of the participants brought their Actigraphs to us, while the other half of the group had their Actigraphs picked up by a courier service. The instruction letters were provided previously.
- The collection of 24-hour recall data at baseline and six months was added to the protocol and approved in March 2004. The protocol for this data collection is based on similar recalls done in previous studies by members of the study team.
- All questionnaires and data collection protocols are housed in the study's Procedures Manual.

b. Review baseline questionnaires for completeness and for content validity.

- A baseline questionnaire packet was reviewed and compiled. All questionnaires were submitted to the Department of Defense on November 14, 2003. The packet included the following sections:
    - Demographics
    - Food Frequency Questionnaire
    - The Community Health Activities Model Program for Seniors (CHAMPS)
    - Medical/Family History

- Personal Reaction Inventory (also known as the Marlowe Crowne Social Desirability Scale)
- Martin-Larsen Approval Motivation scale (to measure social approval)
- Perceived Stress Scale
- Anger Expression Scale

- The Perceived Stress Scale was approved to be added the baseline questionnaire packet. This questionnaire allowed for better assessment of how individuals react to stress, versus simply listing the number of potentially stressful events to which they have been exposed.

c. Revise baseline questionnaire to assess demographic, health history, and family health history, as necessary.

- Questionnaires were reviewed by Dr. Wilcox and Dr. Heiney to assess for readability in this population.
- On their recommendation, the font of all questionnaires was changed to Times New Roman, type size 14.

d. Hire and train the Project Coordinator, Research Nurse, and other project staff.

- A Project Coordinator trained in nutrition and exercise science was hired in August 2003. In the fall of 2004, the role of Project Coordinator was divided into two part-time positions. The original project coordinator transitioned into the role of class instructor for the intervention group and a new project coordinator was hired to handle the everyday operations of the study.
- Due to HIPAA compliance, the Nurse Navigator system at Palmetto Health was used instead of a Research Nurse. The Nurse Navigator system uses a nurse trained in patient education, who is also an employee of the Palmetto Health system, to act as liaison between the urologist/oncologist offices, possible participants and study staff. This system was of limited use in recruitment and we have found going straight through the urologists' offices has produced better results.
- A chef trained in vegetarian cooking was hired in October 2003 in order to develop recipes and a cookbook for the intervention group. This individual completed study-related duties in 2004.
- An instructor trained in mindfulness-based stress reduction was hired in January 2004 to prepare class materials and teach the meditation portion of the intervention classes. The meditation instructor trained the class instructor on mindfulness-based stress reduction and then served as a consultant. Trained phlebotomists were hired to perform blood draws at each clinic and handle the preparation and shipment of biological samples collected.
- Two Benedict College students (a Historically Black College here in Columbia) and two graduate assistants from the University of South Carolina were hired to aid in data entry and other study duties.

e. Develop the study data management systems.

- Under the supervision of Dr. Sue Heiney and Mr. Tom Hurley, Microsoft Access databases were created for recruitment; i.e., in order to track eligibility/ineligibility statistics as well as source of referral.
- A tracking database was also established to track participants' study compliance.

f. Develop the tracking database based on our experience with other intervention studies in the Department of Epidemiology and Biostatistics.

- Tom Hurley, biostatistian in the Statewide Cancer Prevention and Control Program and USC the Department of Epidemiology and Biostatistics with extensive experience in creating and managing Access databases, oversaw the development of the tracking database used by the study.

g. Train staff in all data-related and clinic-based procedures.

- Training sessions were held periodically to train Phlebotomists for the study's clinic.
- All other study personnel involved with data-related and clinic-based procedures were trained upon hire. Periodic updates and reviews were provided in bi-monthly study team meetings.

h. Develop and finalize all laboratory procedures to be used in the trial.

- Dr. Shuk Mei Ho at the University of Massachusetts and Dr. Blask with the Bassett Research Institute has provided protocols for the collection and shipment of the specimens they were analyzed, i.e., blood and urine, respectively.
- A clinic routine, with directions for team members assisting in the clinic appointments, was established and is on file. The clinic routine and script are maintained in the study's procedures manual. These were updated as needed.

i. Finalize all biological sample collection and storage procedures to be used in the study.

- A blood collection, processing and shipping protocol along with a urine collection, processing and shipping protocol were developed and are housed in the study's procedures manual (on file).

j. Establish recruitment procedures for men entering the study.

- A bulleted recruitment outline was provided to Department of Defense contact Donna Ferrandino on March 10, 2004.

k. Establish retention procedures.

- The following retention procedures were outlined in the protocol:
    - Establish a project identity. The study identity EASE – Eating, Activity, and Stress Education was created along with a logo to support the identity. The logo was submitted in March 2003 to Donna Ferrandino.
    - Multiple contacts leading up to consent. The bulleted outline on file details the multiple contacts the study team makes with the potential participant before the individual consents. These contacts include mailings as well as phone calls.
    - Provision of meaningful incentives. $10 gas coupons as well as other incentives were provided to participants each week they were enrolled in the study. The list of incentives participants received was provided previously and is on file.
    - Provision of clear communications and expectations. A brochure was created as a tool for providing clear communications to prospective study participants. Participants were also provided with an overview of the intervention from section

D.10. of the protocol, as suggested by Donna Ferrandino, and a more detailed description of the intervention diet (on file). Projected dates of the intervention and clinic appointments were provided during recruitment and were finalized in the welcome call and reminder letter to the participants. The welcome call script and reminder letter were submitted in March 2004 to Donna Ferrandino.

- Maintenance of between-assessment and intervention contacts. The maintenance included weekly incentives to both intervention and control participants, thank you notes included with each incentive, and phone calls to remind them of clinic appointments.

l. Finalize the intervention protocol.

- An intervention manual was created with an outline, handouts, menu and recipes for each intervention class. A copy of the manual's table of contents was submitted in March 2004 to Donna Ferrandino.
- Personnel to run the intervention were hired (dietitian trained in exercise science, instructor trained in mindfulness-based stress reduction) and a chef trained in specialized vegetarian cooking.

Task 2: Recruitment, Months 5-18:

a. Identify men who could be eligible for the study from the tumor registry and patient records at the collaborating urology practices in Columbia, SC.

- The tumor registry was not utilized due to vital information needed to be able to reach potential participants was not available through this resource.
- As of 30 April 2007, 58 patients who were eligible and willing to participate have been referred to the study by collaborating urologists in the Columbia, SC area.
- Dr. Heiney also sent a general mailing to the 430 PrCA patients with whom she works at Palmetto Health Richland. Mailings were also sent to patients of Lexington Urology Associates and Orangeburg Urology Associates this year in order to recruit patients. Some patients were recruited from the Prostate Cancer Survey mailed by the South Carolina Central Cancer Registry to prostate cancer patients who were diagnosed in the eight-country area around Columbia.
- The University of South Carolina's public relations department provided, and IRB approved, Public Service Announcements to area radio stations and newspapers (on file).
- In addition to the above recruitment efforts, various cancer advocates around the state have been given the study brochure and are distributing them at area events and doctor's offices. Brochures were provided at the South Carolina Cancer Alliance (SCCA) annual meeting, cancer presentations in Greenville, South Carolina, area members of the American Urological Association (AUA), and Dr. Thomas Keane's (Chief of Urology) office at the Medical University of South Carolina (MUSC). Dr. Keane asked specifically to be able to refer eligible patients and distribute the study brochure to interested patients in his practice.
- We also utilized the South Carolina Central Cancer Registry in the Summer of 2005 with letters being mailed to potentially eligible participants and surveys being returned indicating their potential interest in the study.
- We also focused recruitment efforts on health fairs, conferences, minority populations via publications targeted for their communities.

b. Among those who say they are willing to participate, confirm eligibility using the criteria listed in section D.2. of the proposal.

- To aid in confirming eligibility of participants. Dr. Heiney and Lynne Bridges developed a checklist, which was mailed to participants. Ms. Bridges then called potential participants and reviewed the checklist with them. All checklists and phone scripts were submitted to Donna Ferrandino on March 2, 2004.

c. Enroll 60 eligible men.

- Currently, we have a database of over 600 men who have been diagnosed with prostate cancer and have been in contact with either by phone or by mail. Of those, 58 men were eligible, agreed to participate, and were able to participate in the study. Of these, 51 represent the sample of men on whom have complete data for all statistical analyses.

d. Establish baseline PSA levels through repeat measures taken before subjects are randomized to intervention.

- Due to HIPAA regulations, previously obtained PSA levels recorded in patient medical records, which would establish a baseline PSA level, cannot be obtained until written permission is obtained from the patient. This permission was obtained during each participant's first clinic visit. After gaining his written consent, we obtained previous PSA levels recorded in his medical charts, if available, as well as collected a blood sample during our baseline clinic for PSA testing by Quest Diagnostics®.

e. Collect data on diet, physical activity, other aspects of lifestyle, demographic, and health (family and personal history), and other factors as outlined in D.4.

- Data collection began on June 9, 2004 and was completed in the Fall of 2006.

f. Schedule the first clinic appointment for the purposes of collecting all of the blood and urine specimens and taking the anthropometric measurements.

- The first group recruited into the study had their first clinic on 9 June 2004.
- These participants were contacted via phone and through letters. The Welcome Call script and letter were submitted to Donna Ferrandino in March 2003.

g. Abstract medical records for relevant health history and pathology data.

- This activity was conducted in the Fall of 2006 and concluded in March 2007. Two graduate assistants worked with the local urologists' and oncologists' offices to obtain this information on the participants.

h. Randomize half of study participants to the intervention condition and half to control by SAS program. Block randomization was done so that cases and controls were matched on age (within 5 years). When randomized to the intervention group, the participants were scheduled to have an individual and group sessions with the interventionist.

Task 3: Intervention / Passive Follow Up in the Controls, Months 8-30:

a. Ensure that the intervention is delivered according to the protocol. This was done by conducting 24-hour recalls (24HR), all of which were reviewed by a member of the study staff.

b. Schedule incentives. Incentives were scheduled and provided on a regular basis to encourage men who were randomized to intervention and their significant other to attend group sessions and other intervention activities.
c. Establish a schedule of reminders to participants regarding the intervention. This was done on a regular basis. We used a reminder call script which is on file.
d. Stay in contact with the control group to assure compliance with the follow-up measures. We continued to maintain contact with the control group, including reminding them of the opportunity to select the intervention in the next available cycle. All subjects (and partners) randomized to control were offered the next available opportunity after there period as a control(s) to participate in the intervention.
e. Schedule clinic visits for the blood, urine, and anthropometric data collection. Throughout the study, we continued to be up to date in the collection of all these data.
f. Assure that all self-assessments are completed at follow up. A regular check of our database a check list was completed in order to ensure that all necessary data were collected.

Task 4: Data Entry, Verification and Interim Analyses, Months 6-31:

a. Assure that all data are immediately read into the tracking and analytic databases. All data were immediately entered into the appropriate data systems.
b. Flag all outlier and illogical responses. All out-of-range or otherwise suspect data were identified and reconciled.
c. Verify all outlier and illogical responses, re-contacting participants, if necessary. All out-of-range or otherwise suspect data were checked and reconciled.
d. Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics). This activity has been on-going since wave C; we are now conducting the final analyses.

Task 5: Final Data Analyses, Months 30-36:

a. Perform all exploratory analyses to test for adherence to model assumptions. We have conducted all descriptive analyses and formal intention-to-treat statistical analyses using all evaluable data collected.
b. Perform all necessary data manipulations (e.g., log transforming all non-normal and heteroschedastic data). This was done as a matter of course in conducting formal analyses of data collected.
c. Test study hypotheses. The formal intention-to-treat analyses were completed in March 2007, after the completion of Wave F.
d. Conduct *post-hoc* analyses of study data. The beginning phases of this occurred when the formal intention-to-treat analyses of data from Waves A to F was completed in March 2007. It is an on-going activity that will result in at least 3 manuscripts in calendar year 2007.
e. Prepare manuscripts. As noted, we are currently working on manuscripts.
f. Archive datasets for future analyses and future patient follow-up. We have begun to do this as part of study shut-down.
g. Plan for future studies. Currently, all data analyses, interpretation, and manuscript-writing activities are conducted with an eye toward the question: What next? This also includes a qualitative data collection process evaluation is ongoing in order to assess the feasibility of conducting similar studies in underserved populations (Process Evaluation Questionnaire – see Appendix 1).

Key Research Accomplishments:

In our first year of funding, we created an intervention manual with twelve weeks of lessons combining instruction in nutrition, mindfulness-based stress reduction (MBSR), physical activity, and behavior change methods. To aid in at-home compliance with the intervention, study personnel created a cookbook and an instructional MBSR audio CD set. Additional accomplishments include the study and procedure manuals, the study's questionnaire packet and study databases. We began our 6th (F) and final wave of participants in April 2006 and ended in October 2006. We also utilized the South Carolina Central Cancer Registry and building a database of PrCA patients. This has aided in the recruitment of participants for this study and will aid in the recruitment of future participants to other studies, thus providing the general population with opportunities heretofore unavailable to men in South Carolina.

We offered intervention classes for the controls who have completed the study and wish to learn about the intervention. And at the request of the participants, we have held a reunion for those who have completed the study.

Reportable Outcomes:

Study products: The study's intervention manual and procedures manual were completed. The study efforts have also produced a vegetarian cookbook and MBSR instructional CD set. Columbia's Cooking!, a program of healthy cooking classes open to the public, began due to interest this study generated in leading a healthier lifestyle. We continue to offer participants of EASE the opportunity to participate in these instructional classes. This new program has also produced a separate cookbook that will be available in summer 2007. Recruitment efforts have aided participating doctor's offices with establishing databases capable of tracking their patients.

Funding applied for and received based on this award: Study biostatistian, Tom Hurley, was awarded a grant by the South Carolina Research Authority and the South Carolina Nutrition Consortium entitled "Self-Reporting of Dietary Data: Influence of Bias and Imprecision on Intervention Effect Estimates." This allowed us to conduct three 24-hour dietary recall interviews for each of the study periods. This provided a huge advantage for the study, as this is the deluxe method of dietary assessment (8-10) and was provided at no cost to the study budget.

Training opportunities: Four interns have had the opportunity to work with this study. These included three dietetic interns from Winthrop University completing part of their community nutrition rotation by working with the study intervention manual and 24HR set-up, and a masters student in the Health, Promotion, Education and Behavior department at the Arnold School of Public Health completing his degree's practicum requirement. Collaborative efforts begun with Benedict College, a HBCU here in Columbia, SC with the hiring of two students. These efforts include hiring their students as research assistants to aid the study in our recruitment efforts within the state's minority population. Also, we have provided training opportunities for two additional Winthrop University dietician interns.

Provisional Final Results (as Reported to the CDMRP Prostate Cancer Research Program 2007 IMPaCT Meeting)

Methods
Complete data were available on a total of 51 men with rising post-treatment PSA. Each man, along with a partner of his choice, was randomized to usual care or an intensive 12-week intervention followed by three monthly booster sessions. Statistical methods included classical intention-to-treat comparisons and *post hoc* analyses included signal detection methods.

Results
The intervention and control groups did not differ statistically by age (about 70 years, on average), race (31.4% non-White overall), education level, employment status, marital status, smoking status, histological grade, type of treatment, relative weight [BMI=weight(kg)/ height(m)^2 = 28.8 in intervention subjects and 29.4 in controls), or PSA at baseline (geometric means of 0.54 and 0.45 ng/ml in intervention and control, respectively). After six months, the intervention group experienced a 32% decrease in saturated fatty acid (SFA) intake vs. a slight increase in the control group ($p<.0001$) and a 155 kcal/day decrease in total energy intake vs. a 98 kcal/day rise in the controls ($p<.05$). Commensurate with this change was a BMI decrease of 0.45 kg/m^2 in the intervention group. Approximately ½ (49%) of men experienced a reduction in PSA at 3 months. Using a simple intention-to-treat repeat measures analysis, no difference in PSA was observed by intervention status. Signal detection methods indicated that among men with a reduction in PSA the strongest associations were with reduced SFA intake (54% experienced a PSA decrease vs. 38% in the high SFA group). Furthermore, 63% of those who increased fruit intake had a PSA reduction vs. only 36% of those who did not increase fruit consumption.

Conclusion
While no change was observed in PSA level over the intervention period using intention-to-treat analyses, positive health changes in a number of lifestyle parameters were observed with the intervention. Additionally, both decreased saturated fatty acid intake and increased fruit intake were associated with reductions in PSA.

Impact
It is expected that the changes associated with the intervention will improve the quality of life of the men in the study and may translate into substantial health benefits with long-term adherence to the intervention recommendations.

Final Results (Will be Reported to the CDMRP Prostate Cancer Research Program as they appear in the peer-reviewed press)

Conclusions:

The study team recruited the 6th and final wave of participants who completed their wave by the end of October 2006. We offered one additional intervention class at the completion of the 6th wave so that the individuals assigned to the control group were given the opportunity to attend the intervention classes. We also offered all control participants the opportunity to take healthy cooking classes (Columbia's Cooking!), which are open to the public but stemmed from the study's interventions.

We continue to utilize the procedures and materials that were put in place for baseline testing and the intervention classes. Recruitment data shows that we exhausted our efforts with the Midlands urologists and we moved out side of the Midlands in order to recruit. To continue a strong recruitment effort and reach as many potentially eligible men as possible, the study team strengthened and created collaborative efforts statewide. We continued to build our database of prostate cancer patients through our collaboration with the South Carolina Central Cancer Registry.

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Appendix

1. EASE Process Evaluation Questionnaire

EASE Process Evaluation Questionnaire

The purpose of these questions is to understand the experiences of the EASE participants from their own point of view. This information will help us make the study better next time around. We're going to ask you questions about your experiences during the recruitment, enrollment, and intervention process. We want to hear both the good and the bad about your experiences.

The following questions are about the participant recruitment and enrollment process.

What were your thoughts and feelings about being in the EASE study **before** speaking to a staff member?

What were your thoughts **after** speaking with the EASE staff?
- Probe: Did you have any worries, concerns, or doubts about the program?
- Probe: Were you excited about the program?

What influenced you to enroll in the study?
- Probe: What was appealing about the study?
  What concerns did you have?

How did having a partner affect your participation in the study?
- Probe: If subject went through with a partner: How would not having a partner with you have impacted your participation? Would you have enrolled?
- Probe: If subject went through without a partner: Tell me about being in the study without a partner.

What are your thoughts about the steps taken to sign you up and get your measurements for the study?
- Probe: What do you think the staff did well?
- Probe: What do you think could be improved on?
- Probe: Was there anything we did that you thought was unnecessary?

The following questions are about the EASE intervention meetings and phone calls.

What were your thoughts after the **FIRST** group meeting?
- Probe: Did you have any worries, concerns, or doubts about the program?
- Probe: Were you excited about the program?
- Probe: What did you think of the group leaders?

What were the limits of having classes meet as a group?
- Probe: would you have preferred the intervention been in a different format?

What were the benefits of having classes meet as a group?

When thinking about the **mindfulness** component of the program, what were the biggest barriers you had to overcome to become more mindful? And how did you go about overcoming those barriers?
- Probe: Did you feel the mindfulness teachings contradicted your religious or spiritual beliefs?
  Did mindfulness interfere with your family interactions?

When thinking about the **physical activity** changes you were being asked to make, what were the biggest barriers you had to overcome? And how did you go about overcoming those barriers?

Probe: Did the physical activity part of the program interfere with your family interactions?

When thinking about the **diet** changes you were being asked to make, what were the biggest barriers you had to overcome? And how did you go about overcoming those barriers?

Probe: Did the diet part of the program interfere with your family interactions?

What are your thoughts on the intervention as a whole?

Probe: What did you find most helpful? (tips, materials, format, etc.)

Probe: What did you find least helpful?

How did participating in the intervention impact your lifestyle today?

Probe: Are there parts that you cannot do today?

Probe: Are there parts that you will never do again?

Probe: Are there parts that you try to do, but still find difficult to do on a regular basis?

Is there anything else you would like to tell me?

What did I not ask that you think I should have asked?

Probe: If they state a question, then ask them the answer.

FOR INTERVIEWER: Please note 2-3 important themes or points that arose from this conversation.